Anthrax
Vaccine
Immunization
Program

Individual Briefing

08 Feb 07

History of the Anthrax Vaccine Immunization Program (AVIP)

- Secretary of Defense ordered the AVIP in Dec 97
- Vaccinations began in Southwest Asia in Mar 98 / Vaccinations began in Korea in Aug 98
- Slowdowns in 2000-01. After supply restored, program resumed 2002
- Injunction issued against DoD in Oct 04
- FDA issues Emergency Use Authorization (EUA) in Jan 05
- FDA formally issues Final Rule/Final Order on 19 DEC 05
- AVIP continued as during EUA: same people, voluntary basis
- Deputy Secretary of Defense issued AVIP policy in Oct 06 to re-established a mandatory program for those in higher risk areas and with special roles; policy allows voluntary vaccinations for other groups
- Under Secretary of Defense for Personnel and Readiness released DoD implementation guidance for the AVIP policy in Dec 06

Current Policy Implementation

- **Vaccinations are <u>mandatory</u> for DoD Servicemembers, emergency essential designated civilians, and contractor personnel performing mission-essential services assigned to:**
  - Central Command area of responsibility for 15 or more consecutive days.
  - Korean Peninsula for 15 or more consecutive days
  - Special units with Bio-warfare or Bio-terrorism related missions
  - Specialty units with approved exception to policy

- **Vaccinations shall begin, to the extent feasible, up to 120 days prior to deployment or arrival in higher threat areas.**

Current Policy Implementation

- Vaccinations are voluntary for DoD Servicemembers who are not in the mandatory groups and have received at least one dose of anthrax vaccine absorbed during or after 1998

- Vaccinations are voluntary for DoD civilians and adult family members; contractors and their accompanying US citizen family members:
  - Residing in Central Command area of responsibility for 15 or more consecutive days

    - or -
  - Residing on Korean Peninsula for 15 or more consecutive days

- DoD Civilian Personnel Management Service concluded notification to National Unions on 12 Jan 07

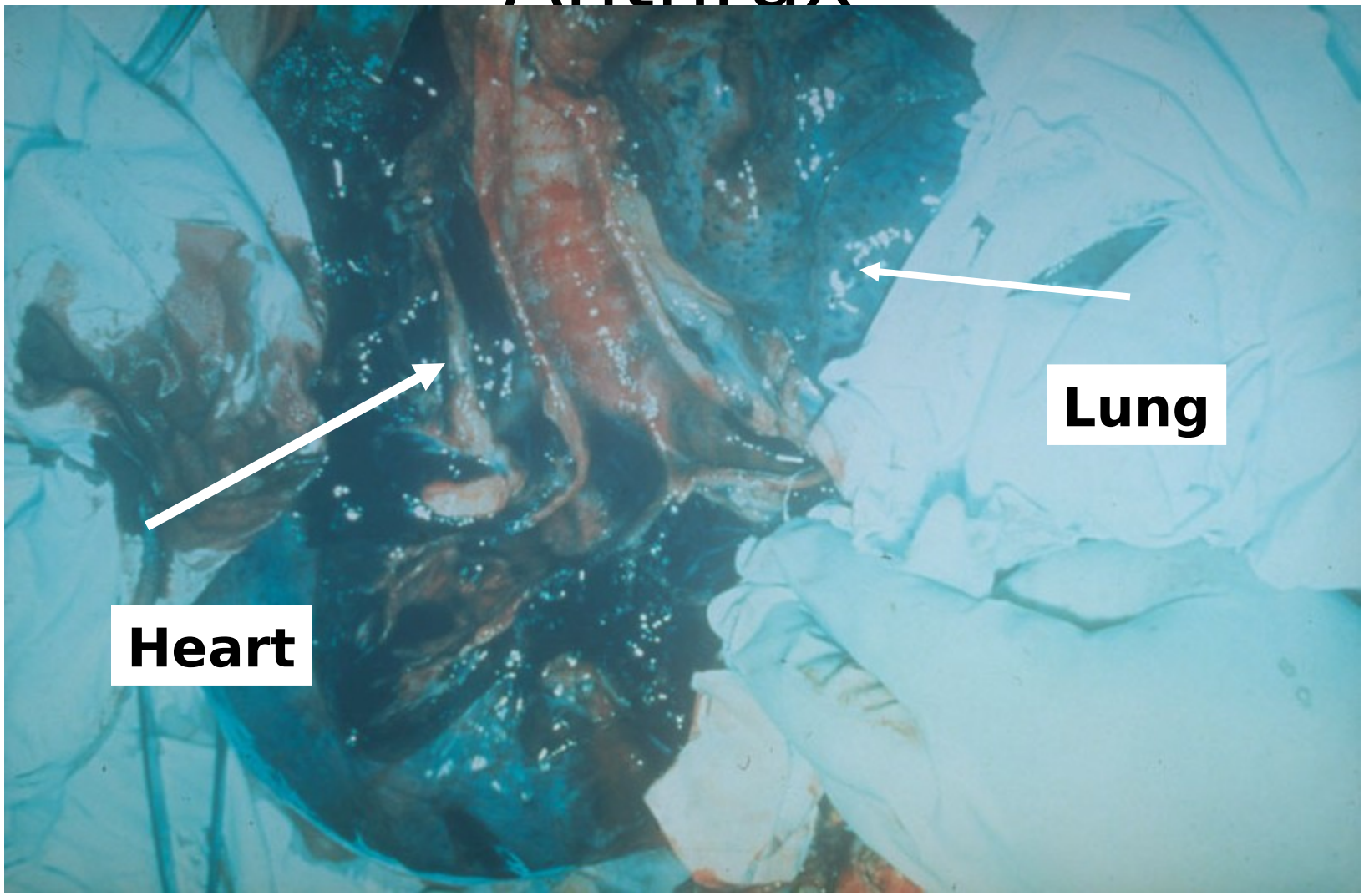
Anthrax Spores

- Highly lethal – Inhaling spores can kill 99% of unprotected, unvaccinated, untreated people
- Extremely stable - withstands harsh conditions, remains inactive for up to 50 years
- Resists heat, ultraviolet light, gamma radiation, bleach
- Easily weaponized and deployed – bombs, missiles, mailed packages, aerosols
- Colorless, odorless, difficult to detect
- At least 7 potential adversaries suspected of researching, developing, or weaponizing anthrax
- You can be infected and not know it, until it’s too late.

Largest Human Outbreak of Anthrax

- Sverdlovsk, USSR, 1979
- Anthrax spores accidentally released from a military microbiology facility
- 77 people infected
- 66 of these people died (86% death rate)
- Most victims worked or lived within 4-kilometer zone south of the city
  - Investigators concluded anthrax spores spread where the wind blew

Lethal Case of Inhalation Anthrax



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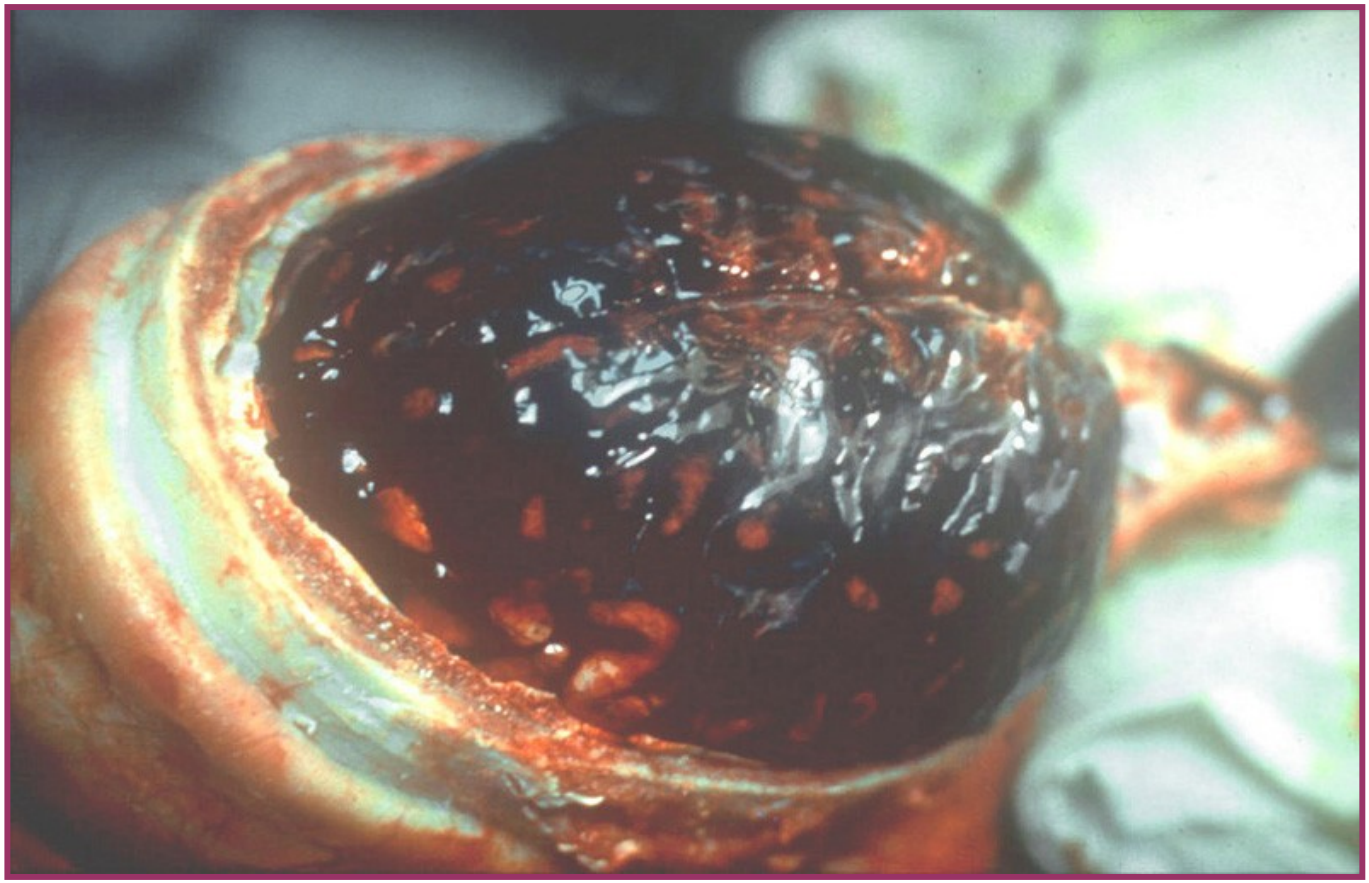
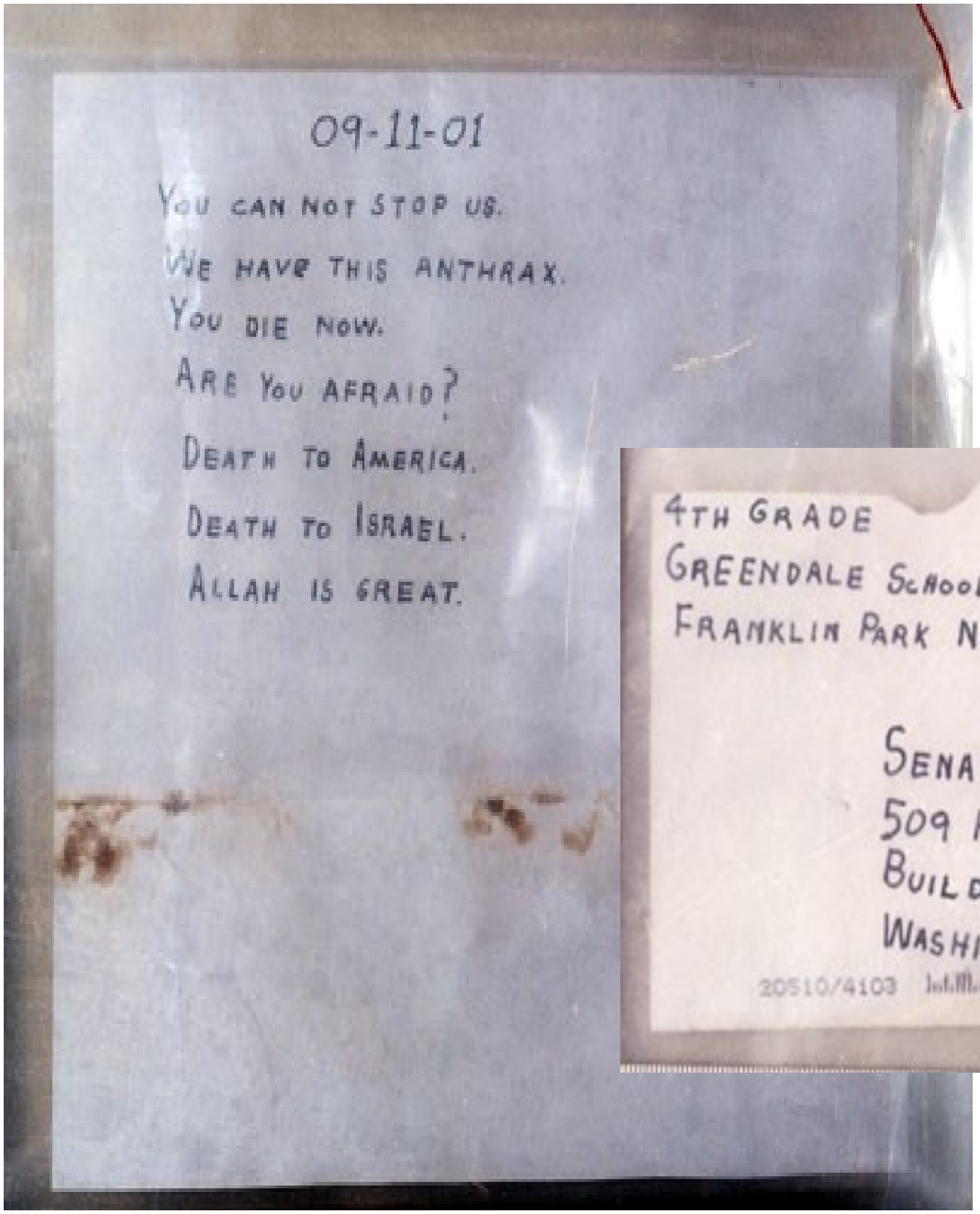


Letter with Anthrax Spores, Fall 2001



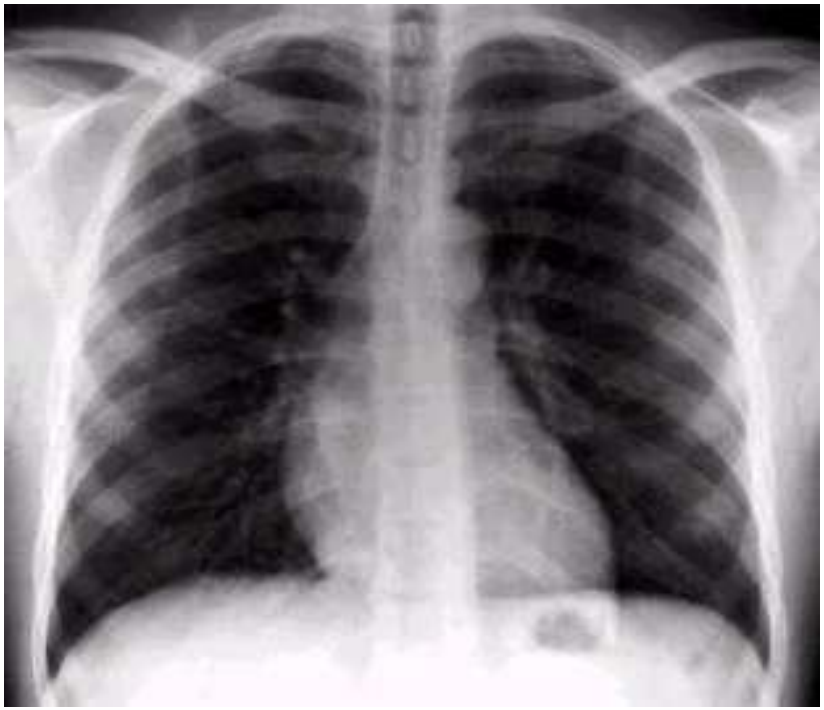
October 2001 Anthrax Attacks

- Several letters containing anthrax spores sent in mail
- 4 regions affected in US
  - Florida
  - New York / New Jersey
  - Washington, DC, metropolitan area
  - Connecticut
- Additional contamination of other postal facilities
- Nationwide effects
- 22 people infected:
  - 11 inhalation cases, 5 died (45% death rate)
  - 11 cutaneous (skin) cases, 7 confirmed cases (including a baby), plus 4 suspected cases
- Over 33,000 people given antibiotics

Timeline of Anthrax Postal Attacks

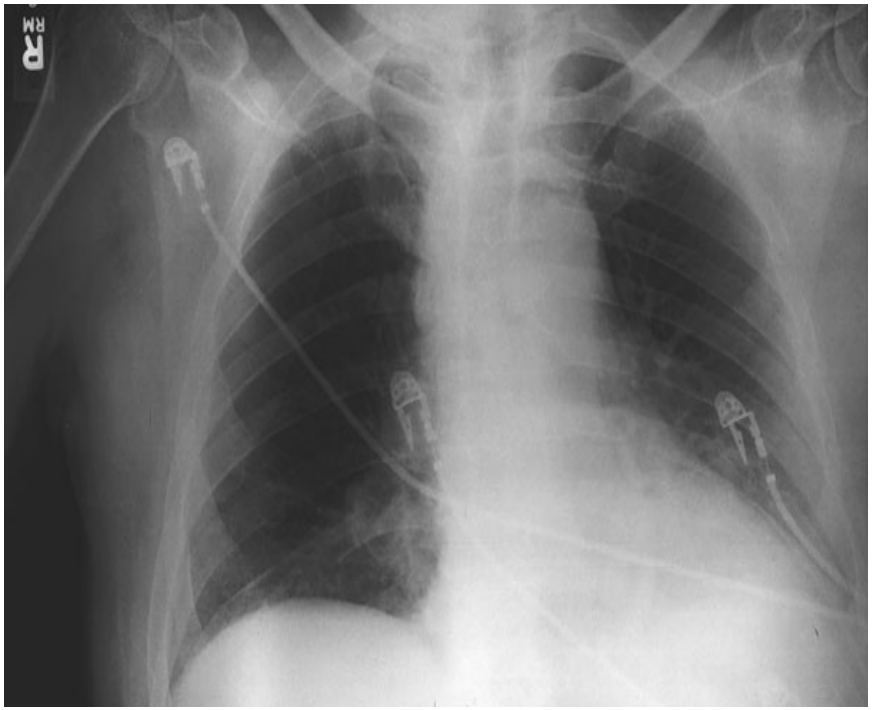
- **4 Oct 01**. American Media Inc. (AMI) photo editor diagnosed with inhalation anthrax. He died the next day.
- **16 Oct 01**. Without knowing they had been exposed, four Washington area postal workers developed inhalation anthrax symptoms. Two died. The Brentwood postal facility is now named the Curseen-Morris Processing & Distribution Center in their memory.
- **25 Oct 01**. A hospital supply worker in New York City with no obvious exposure becomes ill. She died 5 days later from inhalation anthrax.
- **14 Nov 01**. A 94-year-old woman in rural Connecticut with no obvious exposure becomes ill. Diagnosis: inhalation anthrax. She died 1 week later.

Chest X-Ray in Anthrax



Normal Chest X-ray

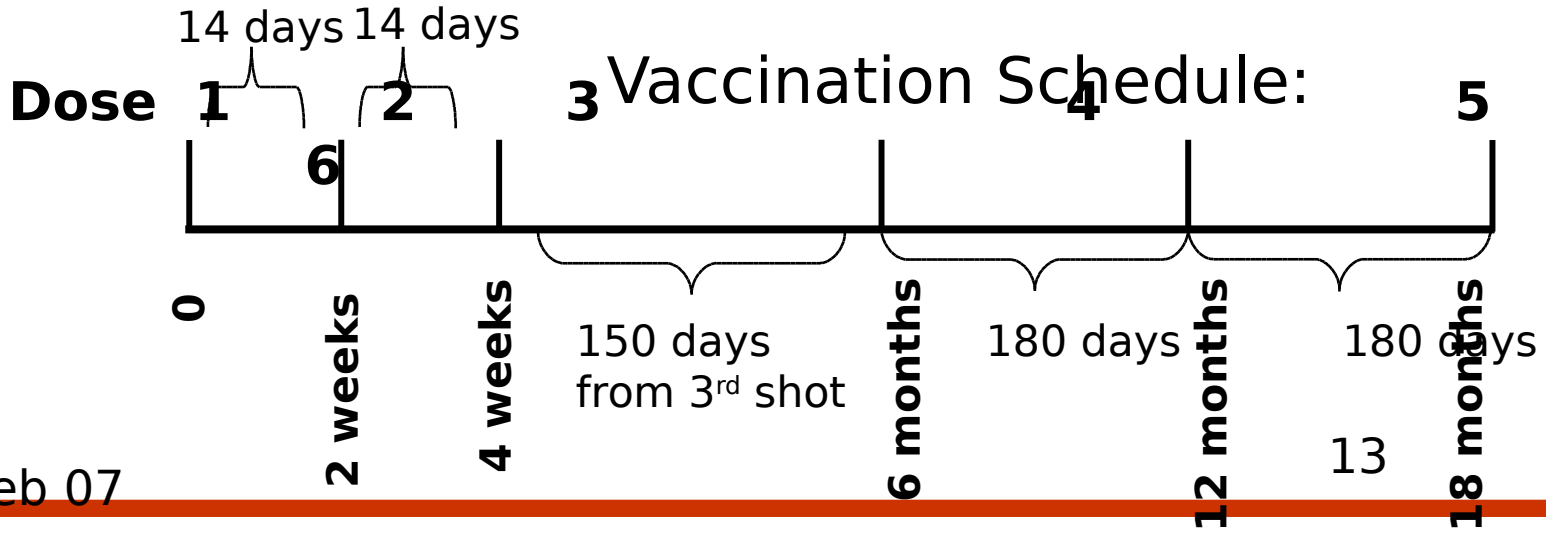
Florida photo editor who died 5 October 2001



Chest X-ray of Inhalation Anthrax Victim

Anthrax Vaccine Facts

- Manufactured by Emergent Biosolutions in Lansing, MI
- A study in mill workers showed anthrax vaccine was 92.5% effective in preventing anthrax (including both cutaneous and inhalation anthrax)
- Each vaccine lot is okayed by FDA before shipment
- No other product is approved by FDA to prevent anthrax before exposure



Anthrax Vaccine Safety

- **Over 1.4 million people vaccinated with over 5.8 million doses**
- **Injection-site reactions common:**
  - 30% of men, 60% of women have injection-site reactions
  - Burning, soreness, redness, itching, swelling, or pain
- **Systemic symptoms (beyond injection site):**
  - 5% to 35% of both genders
  - Muscle or joint aches, headaches, rashes, chills, mild fever, fatigue, swelling may extend below elbow
- **Acute allergic reactions after any vaccine, 1 in 100,000 doses**
- **The risk of any vaccine causing serious harm or death is**

Exemptions from Vaccination

- **Some people should not get anthrax vaccine.**
- **Temporary medical exemptions include:**
  - Women who are pregnant, or might be pregnant
  - Acute diseases, surgery
  - Short-term immune suppression
  - Medical evaluation or condition pending
- **Permanent exemptions can include:**
  - Severe allergic reaction or other serious reaction after a previous dose of anthrax vaccine
  - People with a possible history of latex sensitivity
  - HIV infection or other chronic immune deficiencies
  - People who had Guillain-Barré syndrome (GBS)
  - Recovery from previous anthrax infection

Adverse Event Reporting

- **Vaccine Adverse Event Reporting System (VAERS):**
  - FDA and CDC review 100% of adverse-event reports
  - All VAERS forms reviewed by independent panel of expert civilian physicians for 4 years
- **DoD <u>requires</u> healthcare workers submit a VAERS Form for:**
  - Loss of duty 24 hours or longer (≥ 1 duty day)
  - Hospitalization
  - Suspected vaccine vial contamination
- **Other submissions are <u>encouraged</u>.**
- **<u>Anyone</u> can submit a VAERS Form !**
- **VAERS Forms may be obtained from:**
  - Your clinic, 1-800-822-7967, or www.vaers.hhs.gov

Reserve Component Adverse Events

- **Adverse events after DoD- or USCG-directed vaccinations are line-of-duty conditions**
- **Someone with an adverse event in a non-duty status possibly associated to any vaccination:**
  - Seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary
  - Report the event to your unit commander or designated representative as soon as possible
  - Consider VAERS submission
- **Commander will determine Line of Duty and/or Notice of Eligibility status, if required**

Key Messages

- Your health and safety are our #1 concern.
- The threat from anthrax spores is deadly and real.
- America’s best scientists say that anthrax vaccine protects against all forms of anthrax disease and is safe.
- Vaccination protects you, your unit, and your mission.

For More Information

- Military Vaccine (MILVAX) Agency
  - Website: www.anthrax.mil www.vaccines.mil
  - Toll-Free: 877.GET.VACC
  - E-Mail: vaccines@amedd.army.mil

- For medical advice about <u>your</u> vaccination (24/7)
  - DoD Vaccine Clinical Call Center: 866.210.6469

- For clinical consultation or exemption assistance
  - Website: www.vhcinfo.org
  - E-Mail: askVHC@amedd.army.mil

- CDC National Immunization Hotline